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Biocompatibility evaluation of breathing gas pathways in healthcare applications —

Part 3: Tests for emissions of volatile organic compounds (VOCs)

Évaluation de la biocompatibilité des voies de gaz respiratoires dans les applications de soins de santé —

Partie 3: Essais concernant les émissions de composés organiques volatils (COV)

Reference number
ISO 18562-3:2017(E)

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of ISO standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.

A list of all parts of the ISO 18562 series can be found on the ISO website.

Introduction

This document is intended to protect PATIENTS connected to MEDICAL DEVICES from excessive amounts of VOLATILE ORGANIC COMPOUNDS (VOCS) that arise from within the GAS PATHWAYS of those MEDICAL DEVICES. This document represents the application of the best-known science by addressing the RISKS from potentially hazardous VOCS being conveyed to the PATIENT by the gas stream.

This document is intended to cover the biological evaluation of GAS PATHWAYS of MEDICAL DEVICES within a RISK MANAGEMENT PROCESS, as part of the overall MEDICAL DEVICE evaluation and development. This approach combines the review and evaluation of existing data from all sources with, where necessary, the selection and application of additional tests.

In general, the ISO 10993 series[1] is intended to cover the biological evaluation of MEDICAL DEVICES. However, the ISO 10993 series does not appropriately address the biological evaluation of the GAS PATHWAYS of MEDICAL DEVICES. For example, the ISO 10993 tests do not detect VOCS.

It is not within the scope of this document to address contamination arising from the source of the breathing gases entering such MEDICAL DEVICES, but rather only address the potential contamination generated from within the MEDICAL DEVICE itself. This contamination might be from the original manufacturing PROCESS or generated by the MEDICAL DEVICE itself during use.

This document is concerned with VOLATILE ORGANIC COMPOUNDS that could be conveyed to the PATIENT by the breathing gases. VOLATILE ORGANIC COMPOUNDS can have health effects ranging from unpleasant odour and irritation of the mucous membranes to possible long-term effects on the nervous system. It is accepted that there is no point in setting levels that are lower than those found in air that people might breathe every day.

The tests for the presence of VOLATILE ORGANIC COMPOUNDS generated by respiratory MEDICAL DEVICES are based on advanced laboratory practice and require specialist training and equipment to generate meaningful results.

The methods to determine the acceptable levels of contamination are contained in ISO 18562-1.

In this document, the following print types are used:

— requirements and definitions: roman type;

— informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type;

— *test specifications: italic type*;

— terms defined in Clause 3 of this DOCUMENT or as noted: small capitals type.

In this document, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this document conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

a) “shall” means that compliance with a requirement or a test is mandatory for compliance with this document;

b) “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;

c) “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

The attention of Member Bodies is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication for equipment newly designed and not earlier than 5 years from the date of publication for equipment already in production.

Biocompatibility evaluation of breathing gas pathways in healthcare applications —

Part 3: Tests for emissions of volatile organic compounds (VOCs)

1 Scope

This document specifies tests for the emissions of VOLATILE ORGANIC COMPOUNDS (VOCS) from the GAS PATHWAYS of a MEDICAL DEVICE, its parts or ACCESSORIES, which are intended to provide respiratory care or supply substances via the respiratory tract to a PATIENT in all environments. The tests of this document are intended to quantify emissions of VOCs that are added to the respirable gas stream by the materials of the GAS PATHWAY. This document establishes acceptance criteria for these tests.

This document addresses potential contamination of the gas stream arising from the GAS PATHWAYS, which is then conducted to the PATIENT.

This document applies over the EXPECTED SERVICE LIFE of the MEDICAL DEVICE in NORMAL USE and takes into account the effects of any intended processing or reprocessing.

This document does not address biological evaluation of the surfaces of GAS PATHWAYS that are in direct contact with the PATIENT. The requirements for direct contact surfaces are found in the ISO 10993 series[1].

MEDICAL DEVICES, parts or ACCESSORIES containing GAS PATHWAYS that are addressed by this document include, but are not limited to, ventilators, anaesthesia workstations (including gas mixers), breathing systems, oxygen conserving devices, oxygen concentrators, nebulizers, low-pressure hose assemblies, humidifiers, heat and moisture exchangers, respiratory gas monitors, respiration monitors, masks, mouth pieces, resuscitators, breathing tubes, breathing systems filters, Y-pieces and any breathing ACCESSORIES intended to be used with such devices. The enclosed chamber of an incubator, including the mattress, and the inner surface of an oxygen hood are considered to be GAS PATHWAYS and are also addressed by this document.

This document does not address contamination already present in the gas supplied from the gas sources while MEDICAL DEVICES are in NORMAL USE.

EXAMPLE Contamination arriving at the MEDICAL DEVICE from gas sources such as MEDICAL GAS PIPELINE SYSTEMS (including the non-return valves in the pipeline outlets), outlets of pressure regulators connected or integral to a medical gas cylinder or room air taken into the MEDICAL DEVICE is not addressed by ISO 18562 series.

This document is intended to be read in conjunction with ISO 18562-1.

NOTE This document has been prepared to address the relevant essential principles of safety and performance as indicated in Annex B.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 7396-1:2016, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

ISO 14971:2007, *Medical devices — Application of risk management to medical devices*

ISO 16000-6:2011, *Indoor air — Part 6: Determination of volatile organic compounds in indoor and test chamber air by active sampling on Tenax TA sorbent, thermal desorption and gas chromatography using MS or MS-FID*

ISO 18562-1:2017, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

ASTM D5466-01, *Standard Test Method for Determination of Volatile Organic Chemicals in Atmospheres (Canister Sampling Methodology)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7396-1, ISO 14971, ISO 18562-1 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

NOTE For convenience, an alphabetized index of all defined terms and their sources used in this document are given in Annex C.

3.1
RATED
<value> term referring to a value assigned by the MANUFACTURER for a specified operating condition

[SOURCE: IEC 60601-1:2005, 3.97]

3.2
THERMAL STABILITY
condition under which the temperature of an object does not change by more than 2 °C over a period of 1 h

[SOURCE: IEC 60601-1:2005, 3.125, modified — “increase” has been changed to “change”.]

4 General principles

4.1 TYPE TESTS

The tests described in this document are TYPE TESTS. TYPE TESTS are performed on the final MEDICAL DEVICE, a component of the MEDICAL DEVICE or a representative sample of the MEDICAL DEVICE, part or ACCESSORY being evaluated. If representative samples are used, (i.e. manufactured and processed by equivalent methods), consideration should be made regarding whether or not the differences between the representative sample and the final MEDICAL DEVICE or component could affect the results of the test. Testing of representative samples (manufactured and processed by equivalent methods) instead of the final MEDICAL DEVICE should be supported by a description of any differences between the representative sample and the final MEDICAL DEVICE, and a detailed rationale for why each difference is not expected to impact the BIOCOMPATIBILITY of the final MEDICAL DEVICE.

NOTE Some AUTHORITIES HAVING JURISDICTION evaluate these differences and rationales.

4.2 General

All GAS PATHWAYS from which the PATIENT inspires gas shall be evaluated using the strategy detailed in ISO 18562-1.

The fundamental consideration in assessing a substance is “what is the dose to the PATIENT of this substance?”

Limits for toxicological purposes are most often quoted in µg/d (TOLERABLE EXPOSURE). Limits for environmental purposes, and the quantity that is measured by test laboratories, are usually quoted as concentrations in µg/m^3. To calculate the permitted concentration of that substance (in µg/m^3) in the breathing gas, the total volume of gas inhaled in a day is required. The dose to the PATIENT depends on the concentration of the substance (in µg/m^3) multiplied by the volume (in m^3) inhaled by the PATIENT.

Standard daily breathing volumes are found in ISO 18562-1:2017, 6.3.

5 * VOC emissions

5.1 General

All GAS PATHWAYS from which the PATIENT inspires gas shall be evaluated for VOC emissions. The evaluation should use the RISK MANAGEMENT PROCESS to assess if testing is required.

NOTE 1 The evaluation of some components, which are identical in FORMULATION, processing and preparation for use to an existing component of a MEDICAL DEVICE that has been previously tested, might conclude that no further testing is required. Refer to ISO 18562-1:2017, Figure 2.

A MEDICAL DEVICE, part or ACCESSORY shall not add to the gas that could be inspired by the PATIENT VOCs at levels that create an unacceptable RISK to the PATIENT.

NOTE 2 Parts downstream of the PATIENT can be evaluated for VOC emissions if there is a RISK that the PATIENT might inspire gas that has been in contact with them.

If the RISK MANAGEMENT PROCESS determines that testing is required, the tests of 5.3 shall be performed.

5.2 Acceptance criteria

The dose-to-PATIENT of any substance for which a TI is calculated shall be below that TI.

The dose-to-PATIENT of any substance for which a TI is not calculated shall be below the TTC for all values relevant to the exposure category as indicated in Table 1.

When the “first 24-h test” returns a very low value, below that allowed for longer term use, then further tests need not be performed.

EXAMPLE 1 Where the limited exposure dose-to-PATIENT of a substance is below 120 µg/d for a prolonged exposure MEDICAL DEVICE, further testing is not required as shown in Figure 1, green bar E.

EXAMPLE 2 Where the limited exposure or prolonged exposure dose-to-PATIENT of a substance is below 40 µg/d for a permanent contact MEDICAL DEVICE, further testing is not required as shown in Figure 1, green bar D.

Table 1 — TTC limits by exposure

Exposure category	Length of PATIENT exposure	TTC ug/d		
Limited exposure	≤24 h	360	—	—
Prolonged exposure	>24 h and <30 d	360, for first 24 h	120, for the subsequent 29 d	—
Permanent contact[a]	≥30 d	360, for first 24 h	120, for the subsequent 29 d	40, beyond 30 d

[a] Figure 1, green bar E or blue curve G.

5.3 Test method

Perform VOC emission testing as follows.

a) Set up the MEDICAL DEVICE, part or ACCESSORY according to the instructions for use.

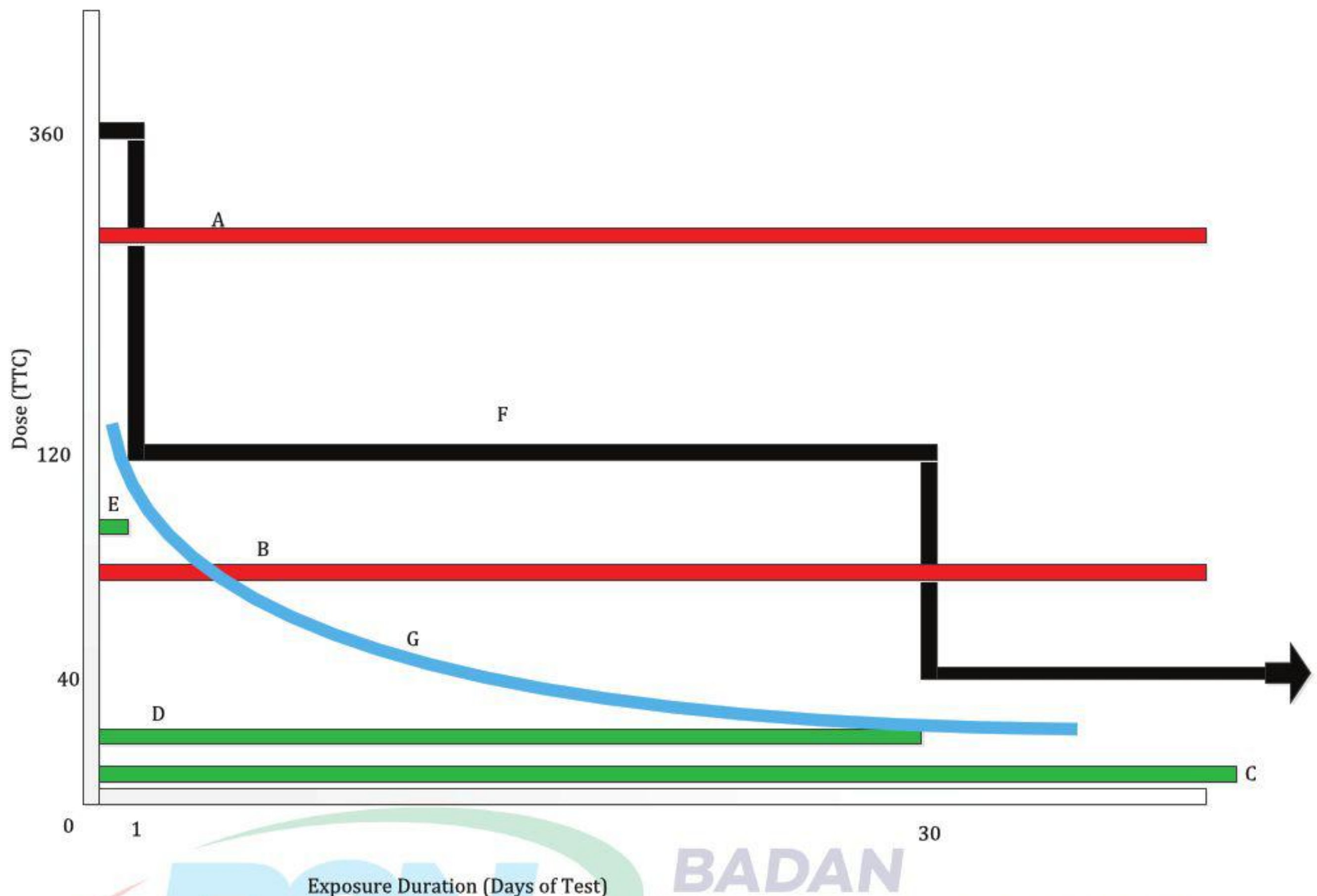
   It can be necessary to use additional ACCESSORIES in order to perform this test (for example, hoses or a test lung). When using such additional items, care needs to be taken to prepare them so that they do not interfere with the measurements being made. Alternatively, the test may be run with all the ACCESSORIES in place, but without the MEDICAL DEVICE under test to produce a blank value. This blank value is then subtracted from the value obtained when running the test again with the MEDICAL DEVICE in the circuit.

   The MEDICAL DEVICE, part or ACCESSORY should be a representative sample that has been subject to normal manufacturing, shipping and handling delays. The tests should be performed at a time after manufacture that represents the shortest reasonable time that could elapse between manufacture and use with a PATIENT.

   It may be necessary to use more than one MEDICAL DEVICE in this test, to allow the results to be greater than the limits of measurement.

b) Maintain the MEDICAL DEVICE, part or ACCESSORY at its highest clinically relevant RATED ambient temperature until the MEDICAL DEVICE, part or ACCESSORY has achieved THERMAL STABILITY.

   NOTE 1 For professional use MEDICAL DEVICES, this is most commonly 21 °C to 25 °C, but in neonatal wards, burn wards and operating theatres, it can be different. MEDICAL DEVICES for the home healthcare environment or emergency medical services environment are often required to work over a wider range of temperatures.

   The test may be performed at higher temperatures to facilitate faster or accelerated testing. However, care is needed to ensure that higher temperatures do not alter the chemical composition of the VOCs emitted.

Key

A (red) — a dose of VOC for which TI is not calculated that would only meet the TTC requirement for a limited exposure MEDICAL DEVICE

B (red) — a dose of VOC for which TI is not calculated that would only meet the TTC requirement for a limited or prolonged exposure MEDICAL DEVICE

C (green) — a dose of VOC for which TI is not calculated that would meet the TTC requirement for a limited, prolonged or permanent exposure MEDICAL DEVICE

D (green) — the limited exposure or prolonged exposure dose-to-PATIENT of a substance is below 40 µg/d for a permanent contact MEDICAL DEVICE; further testing is not required

E (green) — the limited exposure dose-to-PATIENT of a substance is below 120 µg/d for a prolonged exposure MEDICAL DEVICE; further testing is not required

F (black) — acceptance criteria

G (blue) — example VOC decay as a function of time

Figure 1 — Permissible TTC dose as a function of exposure duration

c) Choose a sampling site to be representative of the gas that would be inhaled by the PATIENT. It may be necessary to use a chamber to hold the MEDICAL DEVICE in this test and sample the air in the chamber.

d) * Set the gas flowrate, through the MEDICAL DEVICE, part or ACCESSORY to a value that is representative of the clinical use for the MEDICAL DEVICE, as follows.

1) For continuous flow MEDICAL DEVICES (e.g. ventilator, humidifier):

— intended for adult PATIENTS, use a value of 20 m^3/d;

— intended for paediatric PATIENTS, use a value of 5,0 m^3/d;

— intended for infant PATIENTS, use a value of 2,0 m^3/d;

— intended for neonatal PATIENTS, use a value of 0,21 m^3/d.

The MANUFACTURER may justify a different flowrate, but the justification shall be documented and the flowrate shall be clinically relevant. For example, sleep apnoea breathing therapy equipment and some neonatal ventilators have a very high flow, of which only a portion enters the PATIENT'S lungs, the rest is bypassed.

2) For intermittently used MEDICAL DEVICES (e.g. nebulizer, manual resuscitator) operate the MEDICAL DEVICE in a clinically relevant manner, for the maximum intended duration of a treatment.

3) Choose a sample period that permits capturing sufficient gas to permit making a meaningful measurement.

e) * Sample the breathing gas

NOTE 1 The concentration of emitted VOCs from plastic materials is highest when the parts are new. The emissions of VOCs typically decay over time, as more of them get flushed out of the walls of the GAS PATHWAY as shown in Figure 2. If a measurement is only made at the start of use, then the total dose to the PATIENT can be severely overestimated. Ideally, the sampling could extend over the whole duration of use of the MEDICAL DEVICE, and the total dose the PATIENT receives measured directly. However many current sampling techniques do not allow this. To calculate the dose-to-PATIENT requires calculating the area under the concentration-versus-time curve. To minimize the test burden, the following method for prolonged exposure (>24 h, <30 d) or permanent contact (≥30 d) use MEDICAL DEVICES can be used.

1) For limited exposure (≤24 h), use MEDICAL DEVICES (e.g. nebulizer, manual resuscitator).

Sample for a period that reflects the maximum duration of a typical treatment of a PATIENT in a clinically relevant manner. Either sample continuously or at equally spaced time intervals throughout the duration of use.

2) For prolonged exposure (>24 h, <30 d), use MEDICAL DEVICES.

— For the first sample period, start at the beginning of gas flowing through the MEDICAL DEVICE.

— For the second sample period, sample after the first 24 h of gas flowing through the MEDICAL DEVICE.

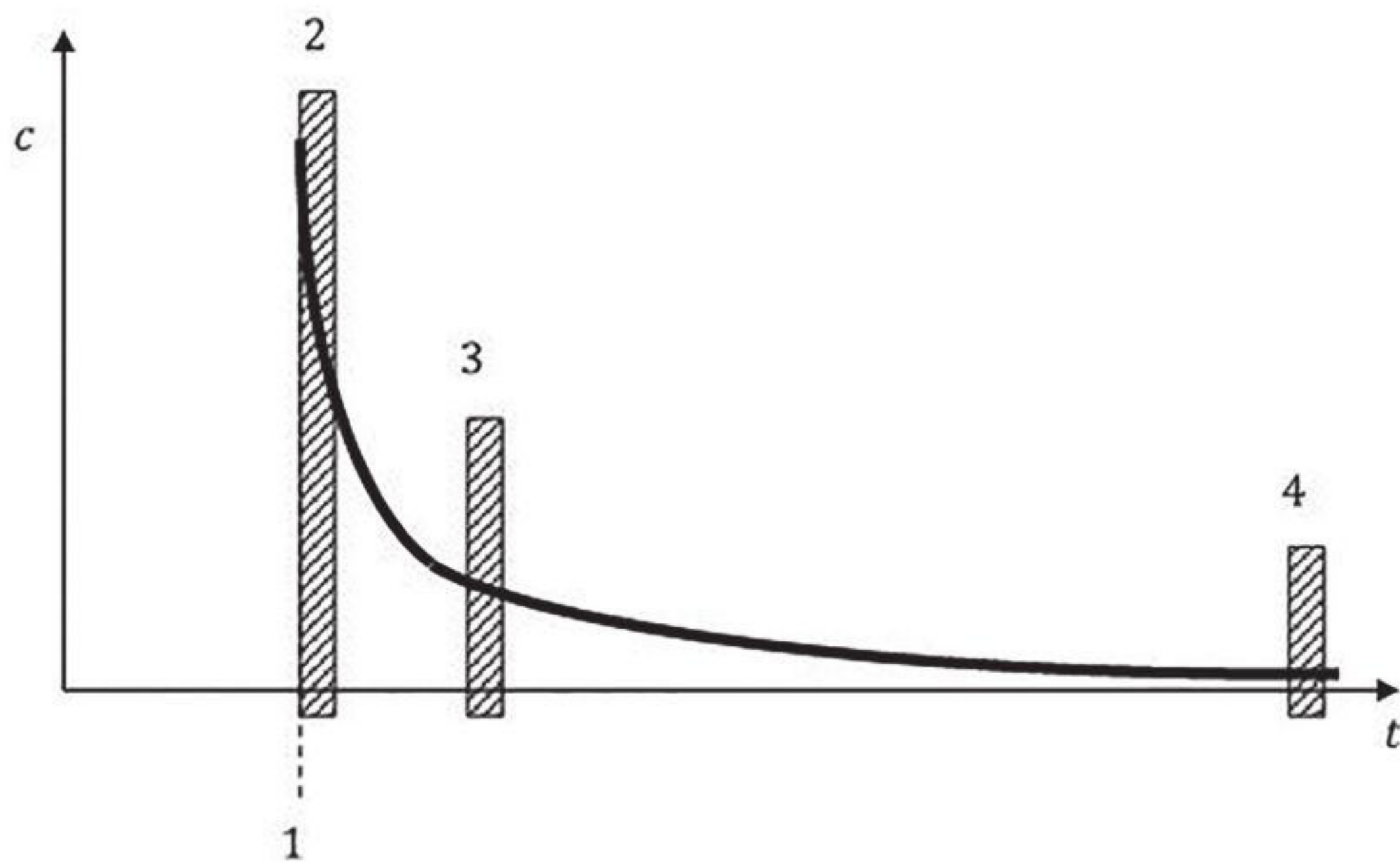
— For the third sample period, start at the end of the duration of use of the MEDICAL DEVICE where the duration of use is the maximum permitted duration of use on a PATIENT, as determined by the MANUFACTURER or upon reaching a value below the TI limit for each substance or the TTC, as applicable.

3) For a permanent exposure (≥30 d) ,use MEDICAL DEVICE.

— For the first sample period, start at the beginning of gas flowing through the MEDICAL DEVICE.

— For the second sample period, sample after the first 24 h of gas flowing through the MEDICAL DEVICE.

— For the third sample period, start at the end 29 d or upon reaching a value below the TI limit for each substance or the TTC, as applicable.

The sample flowrate shall be low enough so as to not disturb the normal operation of the MEDICAL DEVICE.

Key

c concentration
t time
1 start of test
2 sample at start
3 sample at 24 h
4 sample at end of use or at steady state

Figure 2 — Typical decay curve — Concentration as a function of time

The sampling duration may be extended to result in a large enough sample volume to allow quantification down to the required detection limit or reduced to prevent overloading of the sampling system. Additional sampling points may then be needed.

For small MEDICAL DEVICES or others that only emit very low amounts of VOC, it is possible to do a test only at the start. The values at the start are most likely to be higher than the value at the end, so extrapolating this start value across the whole duration of use seriously overestimates the dose the PATIENT receives. If this calculated dose is acceptable, then testing need not be performed throughout the expected duration of use and may be performed only at the start.

Components made of materials that are known not to emit VOCs, such as ceramics or metals, need not be tested for VOCs.

f) Perform analysis of the samples using the methods of ISO 16000-6 or ASTM D5466-01 or a demonstrably equivalent method.

NOTE 2 If there is an indication that there are VVOCs in the analysis according to ISO 16000-6, then further testing using ISO 16000-6:2011, Annex D might be necessary.

g) If added VOCs are detected, identify the compounds and determine the level of each compound present in the samples. Compounds at concentrations below 2 μg/m^3 need not be identified.

NOTE 3 ISO 16000-6 contains information regarding satisfactory levels of identification. Compounds are quantified using the response factor of toluene when individual references are not available or the compound is unidentified.

NOTE 4 Required detection levels for a specific compound can vary, depending on the allowed TOLERABLE EXPOSURE. If the TOLERABLE EXPOSURE is high or the time of exposure is short, then there is no need to use the precise analysis methods necessary for more toxic substances or longer exposures.

h) Calculate the dose that the PATIENT could receive.

   1) For prolonged exposure or permanent contact, use MEDICAL DEVICES by calculating the concentrations of each compound over time (as the concentrations decline with time, as shown in the graph in Figure 2) and combining that with the volumes of gas reaching the lungs of the PATIENT, as specified in d). Calculate the dose the PATIENT receives in the first 24-h period and the dose the PATIENT receives in following 24-h periods.

   2) For limited exposure, use MEDICAL DEVICES by calculating the dose the PATIENT receives of each compound within a 24-h period.

i) Using the method outlined in ISO 18562-1:2017, Clause 7, confirm that the dose the PATIENT receives of any individual VOC does not exceed the daily TOLERABLE EXPOSURE for that compound.

NOTE 5 ISO 18562-1:2017, Clause 7, contains more guidance on calculating TOLERABLE EXPOSURE levels and allowable limits for identified and unidentified compounds.

NOTE 6 The TOLERABLE EXPOSURE for the first 24-h period is higher than for the subsequent 24-h periods.

j) If the dose to the PATIENT of one or more compounds exceeds the TOLERABLE EXPOSURE, then the materials and manufacture of the MEDICAL DEVICE should be reviewed. If it is not practicable to alter the materials or manufacture and the MEDICAL DEVICE, perform the analysis as described in ISO 18562-1:2017, Clause 8. If the MANUFACTURER determines that the benefit outweighs the RISKS, then the MEDICAL DEVICE complies with this document.

NOTE 7 Some authorities having jurisdiction assess the biocompatibility evaluation.

Annex A
(informative)

Rationale and guidance

A.1 General guidance

This annex provides rationale for the important requirements of this document and is intended for those who are familiar with the subject of this document, but who have not participated in its development. An understanding of the reasons for the main requirements is considered to be essential for its proper application. Furthermore, as clinical practice and technology change, it is believed that rationale for the present requirements will facilitate any revision of this document necessitated by those developments.

The clauses and subclauses in this annex have been so numbered to correspond to the clauses and subclauses in this document to which they refer. The numbering is, therefore, not consecutive.

A.2 Rationale for particular clauses and subclauses

Clause 5 — VOC emissions

VOLATILE ORGANIC COMPOUNDS should not outgas in excessive amounts from the GAS PATHWAYS into the flow of gases intended to be delivered to the PATIENT. The amount delivered to the PATIENT should not create an unacceptable RISK.

VOCs in the body are characterized by rapid uptake and equally rapid elimination. When the compound is absorbed into the blood stream, it is rapidly distributed throughout the body. The elimination half-lives for VOCs from the blood are typically a few minutes to a few hours.

The most relevant parameter is the actual dose-to-PATIENT — the concentration multiplied by the volume the PATIENT inhales or ingests.

5.3 — Test method

d)

The sources of the test daily flow volumes in this document are described in ISO 18562-1:2017, 6.3 and the accompanying rationale for the subclause. The first usage is expected to yield the maximum extraction of VOCs and therefore conveys the maximum dose of each substance to the PATIENT.

e)

Common sampling durations range from 30 min to 180 min. The sampling duration chosen needs to allow averaging (e.g. of heater wire control algorithms) and smoothing of any transients in the measurement. The sampling duration might need to be longer to result in a large enough sample volume to allow quantification down to the required detection limit or reduced to prevent overloading of the sampling system. Additional sampling points are then advisable.

Annex B
(informative)

Reference to the essential principles

This document has been prepared to support the essential principles of safety and performance of GAS PATHWAYS as components of MEDICAL DEVICES according to ISO 16142-1[2]. This document is intended to be acceptable for conformity assessment purposes.

Compliance with this document provides one means of demonstrating conformance with the specific essential principles of ISO 16142-1. Other means are possible. Table B.1 maps the clauses and subclauses of this document with the essential principles of ISO 16142-1.

Table B.1 — Correspondence between this document and the essential principles

Essential principle of ISO 16142-1:2016	Corresponding clause(s)/ subclause(s) of this document	Qualifying remarks/notes
8.1 a)	Clause 4, Clause 5	Only the part relating to toxicity is addressed.
8.1 b)	Clause 4, Clause 5	
8.2	Clause 4, Clause 5	
8.4		
8.5		Only the part relating to egress of substances from the MEDICAL DEVICE is addressed.

Annex C
(informative)

Terminology — Alphabetized index of defined terms

NOTE The ISO Online Browsing Platform (OBP)[1] and the IEC Electropedia[2] provide access to many of these terms and definitions.

Term	Source
accessory	ISO 18562-1:2017, 3.1
authority having jurisdiction	ISO 16142-1:2016, 3.1
biocompatibility	ISO 18562-1:2017, 3.2
expected service life	ISO 18562-1:2017, 3.3
formulation	ISO 18562-1:2017, 3.4
gas pathway	ISO 18562-1:2017, 3.5
manufacturer	ISO 14971:2007, 2.8
medical device	ISO 18562-1:2017, 3.11
medical gas pipeline system	ISO 7396-1:2016, 3.29
normal use	ISO 18562-1:2017, 3.9
patient	ISO 18562-1:2017, 3.11
process	ISO 14971:2007, 2.13
rated	3.1
risk	ISO 14971:2007, 2.16
risk management	ISO 14971:2007, 2.22
thermal stability	3.2
tolerable exposure	ISO 18562-1:2017, 3.13
type test	ISO 18562-1:2017, 3.15
voc	ISO 18562-1:2017, 3.16
volatile organic compound	ISO 18562-1:2017, 3.16
vvoc	ISO 18562-1:2017, 3.17

1) Available at: https://www.iso.org/obp/ui/#home

2) Available at http://www.electropedia.org/

Bibliography

[1] ISO 10993 (all parts), *Biological evaluation of medical devices*

[2] ISO 16142-1:2016, *Medical devices — Recognized essential principles of safety and performance of medical devices — Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards*

[3] IEC 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*